

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Suzanna Bowling,

Plaintiff,

—v—

Johnson & Johnson and McNeil Nutritionals, LLC,

Defendants.

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17-cv-3982 (AJN)

MEMORANDUM
OPINION & ORDER

ALISON J. NATHAN, District Judge:

Plaintiff Suzanna Bowling brings this putative class action alleging that Benecol Spread and Benecol Light Spread, manufactured by Defendants, were falsely and misleadingly labeled as containing no trans fat and no trans fatty acid. Defendants have filed a motion to dismiss or, in the alternative, to strike the nationwide class allegations in the complaint. The Court does not deem oral argument necessary to decide the motions. Both motions are denied.

I. BACKGROUND

During the time period at issue in this case, Defendants Johnson & Johnson and McNeil Nutritionals, LLC manufactured Benecol Regular and Light Spreads. Dkt. No. 1 (Complaint) at ¶ 1. The nutrition label on the Benecol Spreads listed the amount of trans fat contained in the Spreads as zero grams. *Id.* at ¶¶ 15, 17. The Benecol Spread containers also displayed a label stating that the Spread contained no trans fats or trans fatty acids. *Id.* at ¶¶ 1, 14-17. However, the Benecol Spreads contained partially hydrogenated soybean oil, which contains trans fats. *Id.* at ¶¶ 15, 17.

On May 25, 2017, Plaintiff filed suit in this case, alleging that Defendants falsely and misleadingly labeled the Benecol Spreads by representing that they contained “no trans fat” and “no trans fatty acids” and by representing that the products were generally recognized as safe for

human consumption. *Id.* at ¶ 1. Plaintiff asserts claims of breach of express warranty, breach of implied warranty of merchantability, unjust enrichment, violation of New York's General Business Law Sections 349 and 350, negligent misrepresentation, and fraud. Plaintiff seeks to represent a class of all persons in the United States who purchased Benecol Spreads, as well as a subclass of all persons who purchased Benecol Spreads in New York.¹ *Id.* at ¶¶ 35-36.

On July 21, 2017, Defendants filed a motion to dismiss Plaintiff's complaint or, in the alternative, to strike the nationwide class allegations. Dkt. No. 11.

II. MOTION TO DISMISS

To survive a Rule 12(b)(6) motion for failure to state a claim upon which relief can be granted, the claimant must provide "a short and plain statement of the claim showing that the pleader is entitled to relief," that "give[s] the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). The allegations must "state a claim to relief that is plausible on its face." *Id.* at 570.

Here, Defendants contend that a conclusion that the Benecol Spread labels were false and/or misleading under state law would conflict with federal law. Accordingly, Defendants argue, Plaintiff's claims are preempted. Defendants assert that Plaintiff's claims are expressly preempted because the National Labeling and Education Act ("NLEA") expressly preempts state laws that impose labeling requirements different from those imposed by federal law, and Plaintiff's claims allege a state law requirement different from the federal one. Dkt. No. 12 (Defendants' Memo) at 5-11. In addition, Defendants assert that Plaintiff's claims are impliedly preempted because "federal law forbade Defendants from doing what Plaintiff alleges state law compels," thereby creating a conflict between federal and state law that is impossible to resolve. Defendants' Memo at 12.

¹ Although not clear from the face of the Complaint, Plaintiff has clarified that the relevant class period is from January 1, 2006, to December 31, 2011. Dkt. No. 25 at 5.

To determine whether Plaintiff's claims are preempted, it is first necessary to set forth the federal statutory and regulatory framework at issue.

A. Federal Regulations

The NLEA establishes uniform food labeling requirements and provides that no state may directly or indirectly establish any requirements for the nutrition labeling of food or for representations about the level of a nutrient in the food that are not identical to the NLEA requirements. 21 U.S.C. § 343-1(a). A state requirement is “not identical” to a federal requirement when the state requirement “directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (i) Are not imposed by or contained in the applicable [federal regulation]; or (ii) Differ from those specifically imposed by or contained in the applicable provision.” 21 C.F.R. § 100.1(c)(4).

Federal Drug Administration (“FDA”) regulations require companies to include certain information on their products’ nutrition labels. *See* 21 U.S.C. § 343(q); 21 C.F.R. § 101.9. The regulation in effect during the class period at issue here provided that, if a serving of the product contained less than 0.5 grams of trans fat, the content of trans fat, “when declared, shall be expressed as zero.”² 21 C.F.R. § 101.9(c)(2)(ii). Similarly, a “label declaration of trans fat content information [was] not required for products that contain[ed] less than 0.5 gram of total fat in a serving if no claims [were] made about fat, fatty acid or cholesterol content.” *Id.* The regulation also provided that, if a statement of trans fat content was not required and thus not declared, “the statement ‘Not a significant source of trans fat’ shall be placed at the bottom of the table of nutrient values.” *Id.*

In addition to nutrition labels, the FDA also regulates “nutrient content claims,” which are statements that a food purveyor may make to characterize the level of a nutrient in the food and which are distinct from the required nutrition labels. *See* 21 U.S.C. § 343(r); 21 C.F.R. § 101.13(b). Nutrient content claims may be “expressed”—a “direct statement” about the level

² See Dkt. Nos. 24 & 25.

of the nutrient, like “contains 100 calories”—or “implied”—a statement that, for example, suggests a nutrient is present or absent in a certain amount, like “high in oat bran.” 21 C.F.R. § 101.13(b)(1), (2)(i). Companies may use reasonable variations in spelling and synonyms in making nutrient content claims, provided that they are not misleading. 21 C.F.R. § 101.13(b)(4).

FDA regulations permit statements about the amount or percentage of a nutrient if the statements do not “implicitly characterize the level of the nutrient in the food” and are not “false or misleading in any respect (e.g., ‘100 calories’ or ‘5 grams of fat’).” 21 C.F.R. § 101.13(i)(3). If a product contains less than 0.5 grams of fat per serving, companies may make claims that the product is, *inter alia*, “fat free,” has “no fat” or “zero fat,” or is a “negligible source of fat.” 21 C.F.R. § 101.62(b)(1). Similarly, terms like “saturated fat free,” “no saturated fat,” and “zero saturated fat” may be used when a serving contains less than 0.5 grams of saturated fat and less than 0.5 grams of trans fatty acid. *See* 21 C.F.R. § 101.62(c)(1). There is no comparable regulation expressly authorizing “no trans fat” nutrient content claims.

B. Preemption

If, as Defendants contend, federal regulations authorize “no trans fat” statements when the amount of trans fat in a product is greater than zero grams but less than 0.5 grams, then a state law that characterizes such assertions as false or misleading would conflict with federal law. If, on the other hand, the FDA regulations do not permit “no trans fat” statements, then there would be no conflict if a state law prohibited them. Accordingly, it is necessary to determine whether federal law authorizes “no trans fat” statements.

Although the Second Circuit has not addressed that question, two other circuits have, and they have specifically analyzed whether federal regulations permit Benecol’s “no trans fat” statements. The Third Circuit held that they do—and, thus, that state law causes of action alleging that “no trans fat” assertions are false or misleading are preempted, *see Young v. Johnson & Johnson*, 525 F. App’x 179 (3d Cir. 2013), whereas the Ninth Circuit held that they do not—and, therefore, that the state law causes of action are not preempted, *see Reid v. Johnson*

& Johnson, 780 F.3d 952 (9th Cir. 2015). Although those decisions are not binding on this Court, it is nonetheless helpful to consider their reasoning.

1. The Third Circuit

Like the plaintiff here, the plaintiff in *Young v. Johnson & Johnson* alleged that Benecol's representation that it contained "no trans fatty acids" was false and misleading because Benecol contains small amounts of trans fats. 525 F. App'x at 181. The plaintiff argued that, "although the regulations authorize Benecol to claim that it contains '0g of Trans Fat Per Serving,' they do not expressly permit a claim of 'NO TRANS FAT' for the product as a whole." *Id.* at 182. The plaintiff emphasized that he sought to prohibit false and misleading claims about trans fat content "*per product.*" *Id.* (emphasis in original).

The Third Circuit rejected the plaintiff's argument. It observed, "Benecol contains less than 0.5 grams of trans fat per serving, and therefore properly discloses that it contains '0g of trans fat' per serving in the Nutrition Facts box." *Id.* The Third Circuit acknowledged that federal regulations did not explicitly permit the advertising of a product as containing "no trans fat," but it emphasized that the regulations generally allowed "statements[s] about the amount or percentage of a nutrient" if they were not "false or misleading" and specifically allowed "no fat" and "no saturated fat" nutrient content claims "without reference to a per-serving limitation, provided that the product indeed contain[ed] less than 0.5 grams per serving." *Id.* at 182-83. The court noted that FDA regulations "authorize[d] nutrient content claims based on per serving amounts, even if those claims [were] not entirely accurate on a per product basis." *Id.* at 183. Consequently, the Third Circuit concluded that "even if a 'no trans fat' claim [was] not expressly contemplated by the regulations," the statement was not "misleading" under federal law. *Id.* The Third Circuit held that because federal regulations authorize "no trans fat" nutrient content claims, the plaintiff's action was preempted. *Id.*

2. The Ninth Circuit

As in *Young*, in *Reid v. Johnson & Johnson*, the plaintiff alleged that Benecol's "no trans fat" assertions were false. 780 F.3d at 957. In determining whether the "no trans fat" statement

was authorized by federal regulations, the Ninth Circuit discussed two warning letters from the FDA, which stated that “no trans fat” and “trans fat free” were “unauthorized nutrient content claim[s].”³ *Id.* at 962. In addition, the court observed that federal regulations prohibit “false or misleading” nutrient content claims, and it explained that “[b]ecause Benecol contains *some* trans fat (between 0 and 0.5 grams per serving), its ‘No Trans Fat’ claim is misleading.” *Id.* Furthermore, the court noted that the FDA “expressly allowed ‘No Fat’ and ‘No Saturated Fat’ claims for products that contain less than 0.5 grams of fat or saturated fat per serving,” but it had “explicitly decided” not to authorize such representations regarding trans fat. *Id.* Indeed, the court pointed to the FDA’s 2003 decision not to authorize a “no trans fat” nutrient content claim “in light of a lack of scientific information.” *Id.* (citing 68 Fed. Reg. 41,434, 41,464-65). The Ninth Circuit explained that the FDA’s understanding of its regulations as indicated in its warning letters—that “no trans fat” nutrient content claims are not authorized—“makes the most sense of the overall labeling regime.” *Id.* at 963.

In response to the defendant’s argument that the “no trans fat” assertion was merely a synonym for the zero grams of trans fat that it was required to report on the nutrition label, the court explained that nutrition label statements are different from nutrient content claims. *Id.* The court concluded that the FDA’s synonym rule for nutrient content claims did not apply to statements on the nutrition label; in other words, the synonym rule did not authorize the display of nutrient content claims synonymous with nutrition label statements. *Id.*

Because the Ninth Circuit interpreted the FDA regulations as not authorizing “no trans fat” nutrient content claims, it held that the plaintiff’s state law causes of action were not preempted. *Id.*

³ The Court notes that although Defendants are technically correct that the *Reid* court did not take judicial notice of the letters, it explained that it did not need to do so because “[j]udicial notice . . . is unnecessary for materials establishing the legal principles governing a case.” 780 F.3d at 962 n.4.

3. Discussion

The Court finds the Ninth Circuit’s reasoning persuasive and thus concludes that federal regulations do not authorize “no trans fat” nutrient content claims.

In *Young*, the plaintiff framed his argument as one about false and misleading representations regarding the trans fat content *per product*, so the Third Circuit focused its analysis on whether a statement that is accurate on a per serving basis may be rendered false and misleading if made on a per product basis. *See Young*, 525 F. App’x at 182-83. The court assumed that the regulations authorized a “no trans fat” nutrient content claim because 21 C.F.R. § 101.9(c)(2)(ii) required the *nutrition label* to indicate that the food contained zero grams of trans fat if it contained less than 0.5 grams of trans fat per serving.

However, as the Ninth Circuit explained in *Reid*, nutrition label statements and nutrient content claims are different, and they are governed by different regulations. 780 F.3d at 963. Indeed, as the Ninth Circuit noted, the FDA explicitly authorizes “no fat” and “no saturated fat” nutrient content claims but *not* “no trans fat” nutrient content claims. *Id.*

That the regulations expressly authorize “no fat” and “no saturated fat” nutrient content claims but are silent regarding “no trans fat” nutrient content claims suggests that the FDA did not intend to authorize “no trans fat” nutrient content claims. In fact, as the court in *Reid* observed, the FDA considered authorizing such a claim but decided not to do so. 68 Fed. Reg. at 41,464-65. Moreover, the FDA’s warning letters further support the conclusion that its regulations do not authorize “no trans fat” nutrient content claims. Although Defendants argue that the Court should not consider the warning letters, *see* Dkt. No. 21 (Defendants’ Reply) at 5, in deciding a motion to dismiss courts may consider materials that are subject to judicial notice. *Kalyanaram v. Am. Ass’n of Univ. Professors at the N.Y. Inst. Of Tech.*, 742 F.3d 42, 44 n.1 (2d Cir. 2014). However, when a party’s “communications with the FDA are not public records of agency actions” but, rather, “internal documents” that the party “held in confidence,” judicial notice of facts contained in those documents is improper, especially when the authenticity of those documents is disputed. *See Church & Dwight Co. Inc. v. SPD Swiss Precision*

Diagnostics, GmbH, No. 14 Civ. 00585 (AJN), 2014 WL 2526965, at *7 (S.D.N.Y. June 3, 2014). Nevertheless, because in this case the FDA warning letters are publicly available evidence of agency actions, the Court deems it proper to take judicial notice of them. *See In re Frito-Lay N. Am., Inc. All Nat. Litig.*, 12-MD-2413 (RRM) (RLM), 2013 WL 4647512, at *4 (E.D.N.Y. Aug. 29, 2013); *Jones v. Conagra Foods, Inc.*, 912 F. Supp. 2d 889, 900-01 & n.6 (N.D. Cal. 2012); *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 411-12 (S.D.N.Y. 2011). Indeed, although Defendants insist that the warning letters Plaintiff provided may not be the same letters that the Ninth Circuit considered in *Reid*, they do not contend that the letters are not in fact authentic FDA warning letters. *See* Defendants' Reply at 5-6.

The best understanding of the relevant FDA regulations is that they do not authorize "no trans fat" nutrient content claims. Plaintiff's argument that "no trans fat" representations are false and/or misleading in this case is thus not preempted expressly or impliedly by federal law. Accordingly, Defendants' motion to dismiss Plaintiff's complaint as preempted is denied.

C. Unsafe for Human Consumption

Separate from their preemption theory, Defendants also contend that Plaintiff's argument that the presence of trans fat rendered Benecol unsafe for human consumption is "factually incorrect and ignores federal law." Defendants' Memo at 2; *see id.* at 12-14. Plaintiff responds that the Court need not consider that contention at this stage because to succeed on her complaint, Plaintiff "need only allege that the product is mislabeled because it" actually contained trans fat when it stated that it did not. Plaintiff's Memo at 3 n.2.

The complaint alleges that trans fats are harmful and that they are not listed as generally safe for human consumption or as approved food additives. *See* Complaint at ¶¶ 24-30. It is not clear that those allegations are false. Although Defendants are correct that in 2015 the FDA stated that partially hydrogenated soybean oil had generally been considered safe for human consumption *by the food industry*, the FDA also explained that partially hydrogenated soybean oil was not listed as generally safe for human consumption or as an approved food additive *in FDA regulations*. *See* Defendants' Memo at 13; *Final Determination Regarding Partially*

Hydrogenated Oils, 80 Fed. Reg. 34650, 34651 (June 17, 2015). Given the allegations in Plaintiff’s complaint and the limited briefing on this issue, and given that Defendants do not argue that Plaintiff needs the “unsafe for human consumption” theory to succeed on any count in the complaint, the Court declines to decide this issue at this stage. Defendants may renew the argument, if appropriate, at summary judgment.

III. MOTION TO STRIKE CLASS ALLEGATIONS

Defendants contend that even if the complaint is not dismissed, Plaintiff’s nationwide class allegations should be stricken from the complaint. Defendants argue that “variations in state law related to Plaintiff’s fraud- and deception-based claims necessarily render it impossible for the Court to certify a nationwide class for any of Plaintiff’s claims under Rule 23(b)(3).” Defendants’ Memo at 14. According to Defendants, individual issues would “overwhelm” the common ones and thus prevent class certification. *Id.* at 16.

In order “to succeed on a motion to strike class allegations, a defendant must ‘demonstrate from the face of the [c]omplaint that it would be impossible to certify the alleged class regardless of the facts [the] [p]laintiffs may be able to obtain during discovery.’” *Reynolds v. Lifewatch, Inc.*, 136 F. Supp. 3d 503, 511 (S.D.N.Y. 2015) (alterations in original) (quoting *Mayfield v. Asta Funding*, 95 F. Supp. 3d 685, 696 (S.D.N.Y. 2015)). “[M]otions to strike class allegations are often denied as premature” but may be granted if the motion raises issues distinct from those that would be decided at the class certification stage. *Id.* at 511-12.

Defendants’ motion to strike is grounded in the argument that Plaintiff will be unable to satisfy Rule 23(b)(3)’s predominance requirement. See Defendants’ Memo at 14-16. Defendants may very well be right. But that argument is one that can be made at the class certification stage.⁴ At this early stage of the proceeding, the motion to strike the nationwide class allegations is premature. Accordingly, the Court denies the motion.

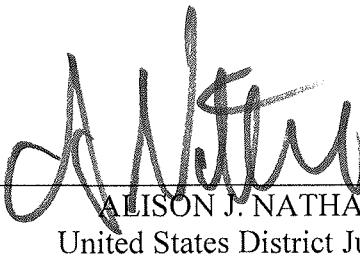
⁴ Defendants emphasize that Plaintiff’s claims under New York General Business Laws cannot be certified on a nationwide basis under New York law. Defendants’ Memo at 16. However, the complaint states that Plaintiff brings those claims individually and on behalf of the proposed subclass. Complaint at ¶¶ 63, 75. The complaint defines the subclass as all Class members

IV. CONCLUSION

The Court denies the Defendants' motion to dismiss or, in the alternative, to strike the nationwide class allegations. This resolves Docket Number 11. An initial pretrial conference is hereby scheduled in this matter for May 4, 2018, at 3pm. The materials discussed at Docket Number 7 are due seven days before that conference.

SO ORDERED.

Dated: March 27, 2018
New York, New York



ALISON J. NATHAN
United States District Judge

"who purchased Benecol Spreads in New York." *Id.* at ¶ 36. Plaintiff thus does not appear to be seeking to bring those claims on a nationwide basis.